K080677

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

SYBRON DENTAL SPECIALTIES

JUN - 6 2008

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz - Contact Person

Date Summary Prepared: March 2008

Device Name:

- Trade Name – ***COMFORTdrive 200XDA Handpieces***
- Common Name – Dental Handpiece and Accessories
- Classification Name - Handpiece, AC-Powered, Dental, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- A-dec/W&H, *Synea Air-Driven Highspeed Handpieces (K070663)*

Device Description:

The *COMFORTdrive 200XDA Handpieces* are dental instruments for use by a trained professional in general dentistry. The handpieces are powered by an integrated electric motor. The devices are re-usable and ergonomically shaped, and can be sterilized by the steam autoclave method.

Intended Use of the Device:

The *COMFORTdrive 200XDA Handpieces* are intended for the removal of carious material, cavities and crown preparations, removal of fillings, and processing of tooth and restoration surfaces. They are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The *COMFORTdrive 200XDA Handpieces* are substantially equivalent to other legally marketed devices in the United States. The intended use of the devices is identical to that of the predicate. The *COMFORTdrive 200XDA Handpieces* are substantially equivalent in design, application and function to the *Synea Air-Driven Highspeed Handpieces* marketed by A-Dec/W&H.

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Claudia Ortiz - Contact Person

Date Summary Prepared: March 2008

Device Name:

- Trade Name - ***COMFORTtronic 4894***
- Common Name – Operative Dental Unit
- Classification Name – Operative Dental Unit and Accessories, per 21 CFR § 872.6640

Devices for Which Substantial Equivalence is Claimed:

- Bien Air., *Optima MX (K042759)*
- Sirona Dental Systems GmbH, *Sirotorque L (K031584)*

Device Description:

The *COMFORTtronic 4894* dental control unit is a stand-alone system for operating electrically-driven handpieces such as the *COMFORTdrive 200XDA*. External power supply provides electric power to the unit. The 4-hole tubing connected to the unit supplies chip/cooling air, water and pressure signal. The speed of the electric handpiece is controlled by air pressure. The control unit is positioned close to a treatment unit at the location preferred by the dentist.

Intended Use of the Device:

The *COMFORTtronic 4894* is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpieces. They are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The *COMFORTtronics 4894* is substantially equivalent to other legally marketed devices in the United States. The *COMFORTtronic 4894* is substantially equivalent in intended use and technical characteristics to the *Optima MX* marketed by Bien Air and *Sirotorque L* marketed by Sirona Dental Systems.

Indications for Use

510(k) Number (if known):

Device Name: COMFORTdrive 200XDA Handpieces

Indications for Use: K080677

The *COMFORTdrive 200XDA Handpieces* are intended for the removal of carious material, cavities and crown preparations, removal of fillings, and processing of tooth and restoration surfaces. They are designed for use by a trained professional in the field of general dentistry.

Prescription Use _____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2008

Kaltenbach & Voigt GmbH
C/O Ms. Claudia Ortiz
Compliance Manager, Regulatory Affairs & Quality Assurance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K080677
Trade/Device Name: COMFORTtronic 4894
Regulation Number: 21 CFR 872.6640 and 872.4200
Regulation Name: Dental Operative Unit and Accessories and Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EIA, EFB
Dated: May 28, 2008
Received: May 29, 2008

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

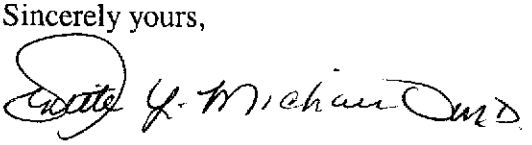
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080677

Device Name: COMFORTtronic 4894

Indications for Use:

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080677